



Syndax to Host Conference Call to Provide Update on the Phase 3 Breast Cancer Trial (E2112) and to Announce its Registration Trial of Entinostat with Keytruda in PD-(L)1 Refractory Non-Small Cell Lung Cancer

October 25, 2018

- **Enrollment completed in E2112; PFS not statistically significant; trial continues as planned having passed 3rd interim analysis for OS with additional planned OS analyses every 6 months -**
- **Company to provide details of its registration-enabling trial for entinostat in NSCLC patients whose disease has progressed on prior chemotherapy and anti-PD-(L)1 treatment -**
- **Martin J. Edelman, M.D., Chair, Department of Hematology/Oncology, Fox Chase Cancer Center, to participate in call on Thursday, October 25 at 4:15 p.m. ET -**

WALTHAM, Mass., Oct. 25, 2018 /PRNewswire/ -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced it will provide an update on E2112, its NCI-sponsored, ECOG-ACRIN led pivotal trial of entinostat plus exemestane in hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer as well as its registration strategy for entinostat in combination with KEYTRUDA® (pembrolizumab) in patients with non-small cell lung cancer (NSCLC), on Thursday, October 25 at 4:15 p.m. ET.

ECOG-ACRIN Cancer Research Group and the National Cancer Institute (NCI) informed the Company that enrollment has completed for E2112. The trial did not achieve the statistical hurdle for the first primary endpoint of improving progression-free survival (PFS) that would have provided the earliest regulatory filing opportunity. ECOG-ACRIN designed and is conducting E2112 to determine whether the addition of entinostat, a class I selective HDAC inhibitor, to exemestane, an aromatase inhibitor, improves PFS and overall survival (OS) in patients with HR+, HER2- breast cancer.

As planned, ECOG-ACRIN is confidentially holding the findings from the PFS analysis until reporting final OS results. After recently performing the third interim OS analysis, ECOG-ACRIN informed the Company that the trial will continue as planned until either it observes an OS benefit or the final target number of events occur. The next interim analysis for the OS primary endpoint is scheduled for 2Q19 with additional interim analyses every six months. Based on the trial design, any positive OS assessment would enable the Company to file for full regulatory approval.

"While the PFS analysis did not show a statistically significant benefit, E2112 was primarily designed to determine whether the combination of entinostat and exemestane could improve OS based on the compelling OS results obtained in the Phase 2b ENCORE 301 trial," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "It was Phase 2b OS results that led to the FDA granting Breakthrough Therapy Designation for this indication and we remain confident in the opportunity for a positive OS trial."

Update on entinostat registration plans in PD-1 / platinum pre-treated NSCLC patients

The Company also provided an update on its regulatory strategy for entinostat in combination with Merck's anti-PD1 therapy, KEYTRUDA® (pembrolizumab) in patients with non-small cell lung cancer (NSCLC) whose disease has progressed after both platinum-based chemotherapy and PD-1 antagonist therapy.

The Company previously presented data from the Phase 2 ENCORE 601 NSCLC cohort that enrolled patients who received prior chemotherapy and anti-PD-(L)1 treatment, at the 2018 IASLC World Conference on Lung Cancer (WCLC) Annual Meeting this past September. Baseline peripheral classical monocyte data were available for 65 of the 72 NSCLC patients evaluable for efficacy and were divided into a group of high baseline monocytes ("monocyte high" n = 19) and low baseline monocytes ("monocyte low" n = 46). The monocyte high subset showed an improved benefit in median PFS (5.3 months vs 2.7 months), and an enhanced objective response rate (ORR, 21% vs 7%). The overall population demonstrated a 10% ORR (95% CI: 4-19%), median PFS of 2.8 months, and median duration of response of 5.3 months. The data also showed a manageable toxicity profile for the entinostat-pembrolizumab combination, with treatment emergent adverse events observed consistent with those previously reported.

"Patients whose disease has progressed despite treatment with PD-1 antagonists represent a very substantial unmet medical need, and efforts to identify novel biomarkers with clinical utility represent one of the most exciting areas of ongoing research," said Michael L. Meyers, M.D., Ph.D., Chief Medical Officer of Syndax. "The proposed trial, which could both validate the use of classical monocytes as a selection criterion and establish the benefits of a new regimen over current standard of care, provides the opportunity for a significant advance for these patients."

The Company announced plans to initiate a randomized registration enabling trial comparing the entinostat-KEYTRUDA combination to standard of care chemotherapy in patients whose disease has progressed after both platinum-based chemotherapy and PD-1 antagonist therapy. Following discussions with the U.S. Food and Drug Administration, the trial is designed to validate peripheral classical monocytes as a marker of response to the entinostat-KEYTRUDA combination and assess whether the combination is superior to standard of care chemotherapy in the high monocyte population. With PFS as the primary endpoint, the Company anticipates beginning the trial in the first half of 2019 and enrolling approximately 200 patients. The Company anticipates top-line data in the second half of 2020, which could lead to regulatory approval both in the U.S. and Europe. The trial will enroll patients with NSCLC whose tumors have progressed following treatment with a PD-1 antagonist and platinum-based chemotherapy.

Martin J. Edelman, Department Chair, Hematology/Oncology, Fox Chase Cancer Center, will join Syndax to discuss the findings from ENCORE 601 during the call at 4:15 p.m. Dr. Edelman is a nationally recognized expert in the treatment and research of lung cancer, and has focused on the development of new agents and biomarkers to personalize lung cancer therapy.

Conference Call and Webcast

The live audio webcast and accompanying slides may be accessed through the Events & Presentations page in the Investors section of the Company's website at www.syndax.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 4088939

Domestic Dial-in Number: 855-251-6663

International Dial-in Number: 281-542-4259

Live Webcast: <https://edge.media-server.com/m6/p/o9ka7y73>

For those unable to participate in the conference call or webcast, a replay will be available for 30 days on the Investors section of the Company's website, www.syndax.com.

About Entinostat

Entinostat, a selective, oral, once-weekly inhibitor of class I histone deacetylases (HDACs), has been shown to resensitize Hormone Receptor positive (HR+) advanced breast cancer to endocrine therapy, and is currently being evaluated in a pivotal Phase 3 clinical trial in combination with exemestane for advanced HR+ breast cancer, an indication for which it has been granted Breakthrough Therapy Designation by the FDA. Entinostat has also been shown to block the function of immune suppressive cells in the tumor microenvironment, and is being evaluated in combination with several approved PD-1/PD-(L)1 antagonists, including in ongoing Phase 2 clinical trials combining entinostat with KEYTRUDA® from Merck & Co., Inc. for non-small cell lung cancer, melanoma and colorectal cancer (ENCORE 601); with TECENTRIQ® from Genentech, Inc. for triple negative breast cancer as well as advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer (ENCORE 602); and with BAVENCIO® from Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer (ENCORE 603).

About E2112

The E2112 trial (NCT0211528) is a randomized, double-blind, placebo-controlled Phase 3 trial of entinostat, Syndax's Class I selective HDAC inhibitor, plus exemestane, an aromatase inhibitor, in patients with hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer who have experienced disease progression following treatment with a non-steroidal aromatase inhibitor (NSAI). The trial, operating under a Special Protocol Assessment was designed, in collaboration with the NCI and ECOG-ACRIN Cancer Research Group, to have two primary endpoints, including progression-free survival and overall survival. The study enrolled a total of 605 patients randomized 1:1 across the two study arms. Syndax is providing the entinostat for the trial under a Cooperative Research and Development Agreement with the NCI.

About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. The Company is developing its lead product candidate, entinostat, a once-weekly, oral, small molecule, class I HDAC inhibitor, in combination with exemestane and several approved PD-1/PD-L1 antagonists. The Company's pipeline also includes SNDX-6352, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, as well as a portfolio of potent and selective inhibitors targeting the binding interaction of Menin with MLLr. For more information, please visit www.syndax.com or follow the Company on [Twitter](#) and [LinkedIn](#).

Syndax's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "believe" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Syndax's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, clinical development and scope of clinical trials and the reporting of clinical data for Syndax's product candidates, and the potential use of our product candidates to treat various cancer indications. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of Syndax's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Other factors that may cause Syndax's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Syndax's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Syndax assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.


KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

Syndax Contacts

Investor Contact
Melissa Forst
Argot Partners
melissa@argotpartners.com
Tel 212.600.1902

Media Contact
David Rosen
Argot Partners
david.rosen@argotpartners.com
Tel 212.600.1902

SNDX-G

 View original content: <http://www.prnewswire.com/news-releases/syndax-to-host-conference-call-to-provide-update-on-the-phase-3-breast-cancer-trial-e2112-and-to-announce-its-registration-trial-of-entinostat-with-keytruda-in-pd-l1-refractory-non-small-cell-lung-cancer-300738263.html>

SOURCE Syndax Pharmaceuticals, Inc.